EUROPEAN COMMISSION

Community Research

SEVENTH FRAMEWORK PROGRAMME

ProGReSS

# Case studies – Overview of Ethical Acceptability and Sustainability (5.1)

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# TABLE OF CONTENTS

# EXECUTIVE SUMMARY

The European Union is increasingly confronted with the challenge of linking ongoing innovation with major societal questions. Delivering European renewal after the financial crisis therefore relies heavily on the advancement of **Responsible Research and Innovation (RRI),** namely research and innovation which is:

1. ethically acceptable,
2. sustainable by avoiding significant adverse effects,
3. and drives towards the common good, i.e., societal desirability.

The PRoGReSS network provides a global perspective on RRI.

This case study report within PRoGReSS focuses on synthetic biology, nanotechnology, and Information and Communications Technology (ICT) as representative examples of modern and emerging technologies. This report provides a briefing for each case study on the first two aspects of RRI: **ethical acceptability** and **sustainability.** The third aspect of RRI, societal desirability, will be the subject of later PRoGReSS reports. Twenty-first century governance of science, innovation and technology must satisfy all three criteria and, whilst PRoGReSS focuses mostly on societal desirability, it is essential that the earlier concepts are integrated in a holistic manner.

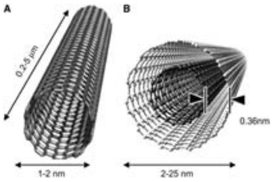
## SYNTHETIC BIOLOGY

Synthetic biology is a young and very dynamic discipline. It is also regarded as an enabling technology, i.e., a technology that enhances other technologies. Ambitious goals include the search for new effective medicines, cheap biofuels and new methods to produce petrochemicals. With its attempts to generate biological systems that might not have any counterparts in existing living systems, it goes beyond genetic engineering.

Compared with other emerging technologies synthetic biology has prompted concomitant ethical research at a remarkably early stage. However, most ethical challenges in synthetic biology are not ingenious to the discipline. They have their parallels in the ethical challenges of other new technologies such as genetic engineering or nanotechnology. However, specifying the exact ethical challenges in the context of synthetic biology is an important task. In addition, some authors argue that there are specific ethical challenges in synthetic biology, referring, for example, to the creation of new life, possibly the most ambitious and contentious goal of the field.

The main ethical challenges can be grouped into biosafety risks (unintended risks) and biosecurity risks (deliberate misuse including dual use). Here the biggest challenges lie in the lack of knowledge about these risks and the high level of uncertainty in risk analysis. Also, challenges to concepts of life and to human self-conceptions are discussed in the literature as well as the challenge to social justice that synthetic biology might raise. Synthetic biology developments will add to the rising demand for agricultural raw material, may lead to competition with food production (where food and biofuel are competing interests) and may

promote forest destruction. In addition, the synthetic production of otherwise naturally derived molecules is likely to have huge effects on trade, particularly in the developing countries. On the one hand, this could – as in the historic example of rubber in Malaysia – destabilize southern economies and employment. On the other hand, this could lead to a higher independence of countries where the production is newly located. In this context the issues of access to the benefits of the technology and intellectual property rights need to be examined. Ethical concerns about synthetic biology are illustrated through the case study of Artemisinin, an anti-malarial drug.




## NANOTECHNOLOGY

Nanotechnology is a relatively new technology that aims to manipulate matter at the nanoscale level. Although nanoparticles were used in medieval times for stained glass windows, the manipulation of matter at the nanoscale level only began in earnest in 1981 with the development of the scanning tunnelling microscope. As synthetic biology, nanotechnology is commonly seen as an enabling technology. One example of this is the role that advances in nanoelectronics have played in the development of computer technology over recent years. Because it is an enabling technology, it has applications in a wide variety of fields including health, materials, electronics, energy, food and agriculture. Much of the work and ethical discussion in nanotechnology concerns nanoparticles and the related carbon nanotubes. These nanoparticles and nanotubes have at least one dimension of 100nm or less and come in a variety of shapes and sizes.

One of the main ethical concerns is a concern about manufactured nanoparticles and whether they pose any health risks. Generally, the concern is not so much that particular nanoparticles are known to pose health (or environmental) risks, but rather that not enough is yet known in order to enable us to understand their effects properly.

Another ethical concern is that nanotechnology may increase the disparity between the developed world and the developing world, with the term “nanodivide” being frequently used. Most of the nanotechnologies focus on the demand of people who can afford to buy new products. Another aspect of the nanodivide concern is that products may be developed and produced in rich countries and may replace natural products currently being produced in poorer countries. As in health, nanotechnology has potential environmental benefits as well as risks. Proposed benefits include purifying polluted water, cleaning up polluted land, and producing sensing devices and technologies to detect pollution at much more refined levels than is currently possible. Another benefit is likely to be the production of cleaner energy, for example through the development of more efficient solar cells. The environmental risks discussed to date have focused on nanoparticles, plants and in particular on health risks to people who come into contact with the particles (e.g. through plants), rather than on immediate risks to the environment. Ethical concerns about nanotechnology are illustrated through the case study of modern sunscreens.

## INFORMATION AND COMMUNICATIONS TECHNOLOGY (ICT)

Information and Communications Technology (ICT) has applications in, and implications for, almost every area of human activity and enterprise. ICT applications may challenge existing social, cultural and ethical norms and may have irreversible consequences for society. The factors which lead to societal benefits may also raise profound ethical issues, in particular if a "technologically deterministic", as opposed to a "societally integrative" model of implementation is applied. Ethical challenges of ICT can be grouped into risks for privacy, concerns about distributive justice, and challenges to human well-being through isolation or confusion about the nature of the self. Some of these concerns are addressed by legislation.

For example in Europe, the use of ICT is heavily regulated in order to protect citizens from a breach of confidentiality or privacy by anyone who has access to or uses an individual's data. However, many ethical issues relate to the inability to access ICT technology, for example through age or other forms of social exclusion. Applications in telemedicine, biometrics and service robots may be (mis)used in ways that benefit professional or family carers but raise ethical issues that have an impact on human dignity and autonomy.

A case study, Ambient Assisted Living (AAL), is presented which focuses on ICT applications which address a grand challenge in Europe (ageing societies) whilst simultaneously raising many ethical concerns.

## AREAS OF ETHICAL CONCERN IN THE LIGHT OF RESPONSIBLE RESEARCH AND INNOVATION

The goal of ProGReSS is to promote a governance framework for Responsible Research and Innovation (RRI) globally. The project will compare science funding strategies and innovation policies in Europe, the US, China, Japan, India, Australia and South Africa. Linking existing RRI networks from all over the world, it is seeking to build support and momentum around a normative model for RRI to foster the convergence of innovation systems at the global level.

The three above-mentioned case studies serve as an instrument to identify ethical categories that might be relevant in science funding strategies and to equilibrate them with the actual challenges of modern and emerging technologies. The results are summarized in Tables 1 and 2. All three cases pose challenges in similar categories – for example health risks or the dual use dilemma. However, in practice challenges within these categories might be quite different. Overall, the ethical concerns of synthetic biology and nanotechnology are often comparable, whereas ICT can pose different problems, since it is more interconnected and apparent in the daily life of people than synthetic biology and nanotechnology are.

**Table 1**: Ethical acceptability

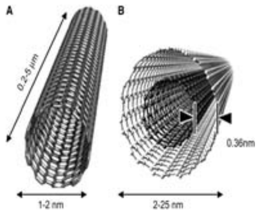
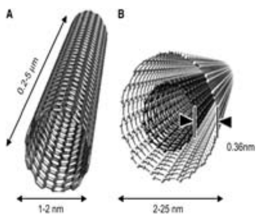
| Synthetic biology<br> | Nanotechnology<br> | ICT<br> |
|---|---|---|
| • Health risks (biosafety risks)<br>• Misuse / dual use (biosecurity risks)<br>• Social justice (multinationals, land grab)<br>• Challenge to the concept of life<br>• Sorcerer's apprentice / "playing god" argument, as a plea for modesty | • Health risks (nanoparticles)<br>• Misuse / dual use (privacy, autonomy risk, terrorist misuse)<br>• Distributive justice (nanodivide)<br>• Challenge to the concept of life (human enhancement, cyborgs) | • Health risks (electromagnetic radiation, failure or crashes in ICT equipment)<br>• Misuse / dual use (violation of autonomy; privacy and data protection breaches)<br>• Distributive justice (access)<br>• Societal dependence on ICT<br>• Challenge to the nature of humanity (physical, mental and emotional enhancement) |

**Table 2**: Sustainability

| Synthetic biology<br> | Nanotechnology<br> | ICT<br> |
|---|---|---|
| • Interference with nature (intended and unintended release)<br>• Environmental risks (biosafety and biosecurity risks)<br>• Resource guardianship (another pressure on biomass) | • Interference with nature (nanoparticles, cyborg-insects)<br>• Environmental risks (nanoparticles) | • Environmental pollution by heavy metals in ICT hardware waste<br>• Increased energy consumption for ICT activity and data storage |

# THE CASE OF SYNTHETIC BIOLOGY

**Synthetic biology is a young and very dynamic field within modern biology. It aims to transform biology into an engineering science and serves as an enabling technology[2]. Its ambitious goals include new effective medicines, cheap biofuels, methods to produce alternatives for petrochemicals, and also the creation of artificial life in the test tube. With its attempts to generate biological systems that may have no counterparts in existing living systems it goes beyond genetic engineering. Compared with other emerging technologies, synthetic biology has prompted concomitant ethical research at a remarkably early stage. In the following section, the current ethical discourse is summarized.**

## FRAMING THE FIELD

In the last six decades biology has changed from a basic, descriptive science to a predominantly applied discipline. The discovery and translation of the genetic code provided the foundation for the first artificial introduction of a gene into an organism, and in 1977 the first human gene was transferred into a microorganism to produce recombinant human proteins[3]. This experiment is often referred to as the advent of biotechnology and genetic engineering.

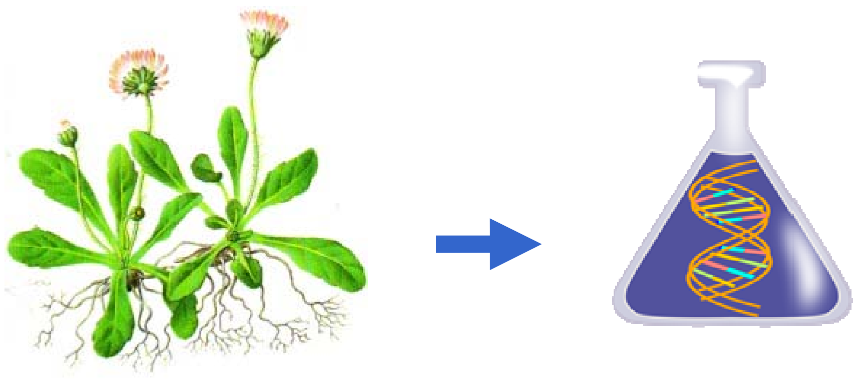


**Fig. 1:** Biology has shifted from a descriptive science to a predominantly applied discipline.

Since then genetic engineering has generated knowledge that has been applied in numerous ways, from the production of single molecules like biopharmaceuticals to the development of transgenic crops that are, for example, resistant to herbicides. Synthetic biology extends beyond genetic engineering: instead of modifying existing biological systems by adding a limited number of genes taken from other species, it seeks to generate new systems from scratch (Engelhard, 2010, 2011).

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[2] An enabling technology is a methodology that provides the means for a user to produce or process something else.

[3] One important example of a recombinant protein is recombinant insulin. Recombinant insulin is synthesized by inserting the human insulin gene into a bacterium *(Escherichia coli),* which then transcribes (reads) that gene and produces human insulin for human use.

Synthetic biology involves the assembly of novel – usually microbial – genomes from a set of standardized genetic parts. These genetic parts may be natural genomic sequences that are being used for a new purpose, natural genomic sequences that have been redesigned to function more effectively or artificial genomic sequences that have been designed and synthesized from scratch. In some cases even the genetic code itself is redesigned. In theory, these systems could have new features that have never previously existed in natural living systems, and they would serve the specified purposes and vision of their creators (Elowitz and Lim, 2010). In short, synthetic biology moves from manipulating to designing living organisms.

Like genetic engineering, synthetic biology has its conceptual roots in the 1970s, but the new achievements of system biology[4] and the automated synthesis[5] of DNA have enabled synthetic biology to flourish in recent years. The beginning of synthetic biology can be dated to the first international conference on synthetic biology in the summer of 2004[6]. Since then synthetic biology has developed rapidly. It exhibits early characteristics of an independent discipline, with its own conferences, scientific journals and university chairs. Nevertheless, there exists no clear-cut and generally accepted definition of synthetic biology. This is not uncommon for such a young and dynamic discipline. Those definitions and explanations that are available are enumerations of different characteristics of synthetic biology and reveal that "synthetic biology" is still an umbrella term. However, they have in common the idea that synthetic biology is the engineering of biology that seeks to rebuild organisms from scratch in order to understand them better and to use them for a wide variety of applications. This engineering approach differs from a biological approach and introduces a different angle to biotechnological research. These ideas are captured in the following working definition:

> "Synthetic biology is the engineering of biology: the synthesis of complex, biologically based (or inspired) systems which display functions that do not exist in nature. This engineering perspective may be applied at all levels of the hierarchy of biological structures – from individual molecules to whole cells, tissues and organisms. In essence, synthetic biology will enable the design of 'biological systems' in a rational and systematic way."

(European Commission, 2005)

At the moment, scientists are developing minimal cells that are stripped down to a few basic features onto which standardized genomic sequences can be mounted expressing the desired function (Forster and Church, 2006; Glass et al., 2006). Some of the ambitious applications envisaged are the creation of bioengineered microorganisms that can produce new medicines, diagnostics and generate petrochemicals; the creation of climate-friendly biofuels, and the creation of hydrogen for the post-petroleum economy (de Lorenzo, 2008;

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[4] "Systems biology" is the study of the interactions between the components of *biological systems,* which typically involves their *in silico* simulations.

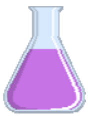
[5] The synthesis of DNA with the help of lab-robots has become less affordable for ordinary laboratories.

[6] The Fifth International Meeting on Synthetic Biology, accessed 14 January 2014.

Lee, Chou, Ham, Lee, and Keasling, 2008; Weber and Fussenegger, 2012; Zhang and Keasling, 2011).

In addition, synthetic biology is expected to generate new information about life processes – from the role of specific genes or of genetic circuits to the metabolism and functioning of a whole organism (Elowitz and Lim, 2010; Silver et al., 2007). Like genetic engineering, synthetic biology is an enabling technology with similar areas of applications. However, scientists hope to achieve these aims more quickly, more cheaply and with a wider range of possible tools and compounds than with traditional techniques. The table below lists the major areas and associated applications of synthetic biology.

**Table 3**: Envisioned applications of synthetic biology

| | |
|---|---|
|  | **Medical applications**<br>• Novel diagnostic tools<br>• Cheaper production of therapeutics<br>• Development of novel strategies for the treatment of disorders such as cancer or infectious diseases, by – for example – vaccine design, microbiome engineering, cell therapy or regenerative medicine |
|  | **Environmental applications**<br>• Living biosensors<br>• Bioremediation[7] |
|  | **Energy**<br>• Biofuels<br>• Biological hydrogen<br>• Artificial photosynthesis |
|  | **Petrochemistry**<br>• Development of new carbon sources for the post-petroleum area |
|  | **Other industries**<br>• Biological computers<br>• Nano-particle production<br>• Responsive materials |
|  | **Verum factum[8]:**<br>• Basic research on the minimal requirements of life |

[7] *Bioremediation* is a waste management technique that involves the use of organisms to remove or neutralize pollutants from a contaminated site.

[8] The principle that truth is verified through creation and invention, not observation.

## AREAS OF ETHICAL CONCERNS

Compared with other emerging technologies, synthetic biology has prompted concomitant ethical discourse and ethics research at a very early stage. Right from the beginning when synthetic biology emerged as a new field, ethical considerations (mainly risk issues) were taken into account by many synthetic biologists themselves. Early ethical and societal research about synthetic biology was partly invited by the field's protagonists, who initially also proposed strategies for self-regulation to govern broader societal discussion. However, non-governmental organizations (NGOs) were quick to warn that regulation could not be left to the scientific community alone and that broader ethical and societal implications needed to be discussed (ETC Group, 2007).

The debate was stirred further when some synthetic biologists used the "creation of artificial life" rhetoric to promote their work. Fear of negative reactions by the public contributed to funding being provided for ELSI activities (Ethical, Legal and Social Implications). Reports were commissioned by governmental bodies to investigate how some of the mistakes and fall-outs known from genetic engineering governance could be prevented. Furthermore, funding institutions and academies of sciences became involved in the discussion. Finally, among academic ethicists, the ethics of synthetic biology is a vivid emerging field (Anderson et al., 2012; Cho, 1999; Dabrock, 2009; Schmidt et al., 2009).

**Box 1:** Distinction of synthetic biology and genetic engineering: new wine in an old bottle?

Depending on the context, distinctions and commonalities of synthetic biology and genetic engineering are discussed differently. For example, historians of science often emphasize commonalities and describe synthetic biology as a continuation of genetic engineering. However, they do the same with the communalities between breeding and genetic engineering. In a legal context distinctions *are* being made – at least in some cases. Whilst most organisms produced by means of synthetic biology can be categorized as genetically modified organisms and are therefore covered by the current framework, some applications in xenobiology – to give an example – are not*. Synthetic biologists themselves tend to categorize synthetic biology as novel and distinct from genetic engineering (sometimes also for funding reasons) whilst emphasizing the similarities between the two fields in the context of risk assessments.

The fields have the *same goals* but *differ in their means.* With its engineering perspective and systemic thinking synthetic biology differs in its approach that opens up a considerable range of novel possibilities. For an ethical and societal evaluation of synthetic biology it is best to differentiate between the *new features* in synthetic biology and the existing ones.

The clearest distinction of synthetic biology and genetic engineering is the much higher *depth of intervention* in synthetic biology. If entities are engineered rather than modified from existing living systems, the reference system in nature becomes remoter and remoter. The scale difference between a few parent organisms or a dozen and more must be taken into account in ethical and societal evaluations.

* For a detailed legal evaluation of synthetic biology see Winter, 2014.

Most ethical challenges in synthetic biology are not ingenious to the discipline. They have their parallels in ethical issues associated with other new technologies such as genetic engineering, nanotechnology or neuroprosthetics. However, contextual discussions within

synthetic biology are an important task. In addition, some authors argue that there are unique ethical challenges in synthetic biology, referring, for example, to the creation of new life (Boldt and Müller, 2008). Most authors propose a risk-benefit and case-by-case evaluation of new synthetic biology developments (Kelle, 2009; Schmidt et al., 2009b).
Ethical challenges can be grouped into biosafety risks, biosecurity risks, and challenges to concepts of life, to human self-conceptions and to social justice.

## BIOSAFETY AND BIOSECURITY RISKS

So far, in most cases statements and discussions on the ethics of synthetic biology have focused on the evaluation and management of direct biosafety and biosecurity risks. While biosafety risks comprise unintended safety issues, biosecurity risks are characterized by deliberate misuse or dual use. The biggest problem in the assessment of biosafety risks of synthetic organisms is their strong divergence from well-known natural systems. In genetic engineering the properties of genetically modified organisms (GMO) are deduced from the characteristics of their well-described parental organisms (typically two or three).

In synthetic biology, however, the number of parental organisms is rising significantly and in the case of artificial genes or gene fragments no well-known parental organisms can be drawn upon. As the number of natural or artificial genes utilized increases, the degree of uncertainty about the behavior of the synthetic organisms in the laboratory, body or environment is rising. When there is no natural reference system, a proven method of technology assessment (familiarity in biotechnology) is no longer applicable.

Another challenge is that the precise characteristics of synthetic organisms remain hard to predict. In addition, genetic circuits tend to mutate rapidly and become non-functional or develop new unknown characteristics. Thus, environmental and health risks are hard to predict. In addition, most organisms utilized in synthetic biology are small organisms like microbes, algae or flies that cannot be retrieved easily once they are released, not even if the release was intended. In response to these problems the utilization of organisms that are not expected to survive outside the laboratory or consist of a different chemistry to the natural one are often cited as a good way of preventing synthetic organisms from intermingling with their environment (Schmidt, 2010). However, these scenarios have not been experimentally validated and their environmental effects could be considerable. In cases of high complexity and uncertainty, the precautionary principle should be applied. This includes, above all, the principle of containment and in some cases even a moratorium.

## DUAL USE AND MISUSE

One main aim of synthetic biology is to make biology easier to engineer by developing a toolbox for the design of biological systems. It is expected that this toolbox will spark a wave of innovation, as more and more people outside the traditional biotechnology community will have the necessary skills and access to relevant materials and information. However, experimenters who are insufficiently educated in biology may lack the foresight to judge risk scenarios and may never have attended biosafety training. In the case of biohackery, garage and do-it-yourself biology, which are upcoming fashions, guidance from scientific supervisors is missing altogether. Efforts to optimize and simplify research and production processes lead to broader access to the technology, since less expertise is needed to perform standard

experiments. This – in itself – is a desired development because it propagates the technology, but it has problematic side effects. Possibilities for dual use and misuse can lead to considerable biosecurity risks, since outlaw states, terrorist organizations, or individuals may get better access to the technology too and may exploit synthetic biology for hostile or malicious purposes (Lentzos, 2012).

## CONCEPTUAL QUESTIONS

Apart from biosafety and biosecurity risks, ethical problems within synthetic biology arise from conceptual questions. Synthetic biology has made initial steps towards the creation of new life from small parts, and it may only be a matter of time before the first *organismus syntheticus* will come into existence. That the creation of life is a realistic option is significant to those pondering ethical questions.

A number of concepts are challenged by this new development: the concept of life, our understanding of nature and the human self-conception (as creator), to name only a few. In many ethical theories, entities that are described as alive are assigned different values or moral standing from artefacts and machines. Consequently, the way in which newly created organisms are conceptualized has an ethical impact on how life in general is understood and valued. Therefore, a properly managed debate that addresses the challenges of synthetic biology requires a problem-oriented and sufficiently consistent definition of living matter with the clearest possible distinction from non-living matter. Semantic problems currently exist, because many advocates of synthetic biology use terms and metaphors (for example 'living machines') that appear to blur the boundary between living and non-living matter. Similarly to this example, our understanding of nature and, therefore, our way of dealing with nature is likely to be changed. When one assumes a dichotomy between nature and culture, one can expect that a change in technical prospects and possibilities will influence the conceptualization of nature, too.

## ‘PLAYING GOD’

Within the societal discussion on synthetic biology it is often argued that scientists should not 'play God'. On first glance this appears to be a religious argument. The theological dispute relates to the consideration of synthetic biology in the light of Genesis 1:1 or rather Genesis 1:28. Does synthetic biologists' creation of life pose unlawful competition with God? Or do synthetic biologists have an obligation to care for God's creation with the help of their tools? (Dabrock, 2009) Often, however, the 'playing God argument' is in fact the 'Sorcerer's Apprentice' argument. As in the phrase “Spirits that I’ve cited / My command ignore” in J. W. v. Goethe's *Zauberlehrling,* it is argued that the scientists might be unable to control their creation and that in real world scenarios sorcerers cannot rewind the mistakes of their apprentices. It is – in summary – an argument for humility in the manipulation of nature.

## SOCIAL JUSTICE

Finally, synthetic biology raises challenges relating to social justice. Developments in the field will add to the rising demand for agricultural raw material and might lead to competition with food production and / or promote forest destruction. In addition, synthetic production of otherwise naturally derived molecules are likely to have considerable effects

on trade, particularly in developing countries. On the one hand, this could – as in the historic example of rubber in Malaysia – destabilize Southern economies and employment. On the other hand, this could lead to a higher independence of countries where the production is now located. In this context the questions of access to the benefits of the technology and intellectual property rights need to be discussed. The ethical discourse summarized above can be ascribed to the first two categories of RRI – ethical acceptability and sustainability – in the following manner:

**Table 4**: Areas of ethical concern in synthetic biology in the light of RRI

| | |
|---|---|
| • Health risks (biosafety risks)<br>• Misuse / dual use (biosecurity risks)<br>• Social justice (multinationals, land grab)<br>• Challenge to the concept of life<br>• Sorcerer's apprentice / 'Playing God' argument, as a plea for modesty | **Ethical acceptability** |
| • Interference with nature (intended and unintended release)<br>• Environmental risks (biosafety and biosecurity risks)<br>• Resource guardianship (another pressure on biomass production) | **Sustainability** |

## SPECIFIC CASE EXAMPLE: ARTEMISININ, AN ANTI-MALARIAL DRUG

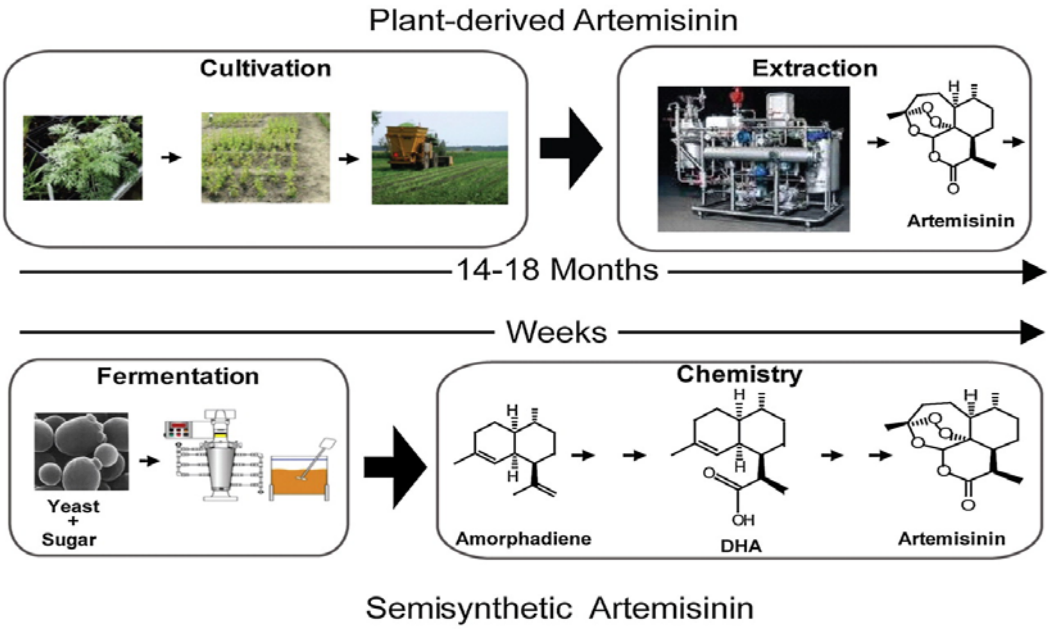
One of the most prominent applications of synthetic biology is the biotechnological production of artemisinin. The leaves of *Artemisia annua,* the sweet wormwood tree, constitute the source of artemisinin, one of the most effective malaria treatments available today. It was discovered in China and is used in traditional Chinese medicine. Since 2005, the World Health Organization recommends artemisinin-based combination therapies as the preferred treatment for malaria.

### TRADITIONAL PRODUCTION

The sweet wormwood plant has until now been the only source of artemisinin. The pharmaceutical industry sources natural artemisinin from thousands of small farmers who grow *Artemisia annua,* primarily in China, Vietnam, Kenya, Tanzania, Uganda, Madagascar and India. The average crop area per farmer in China and Africa is approximately 0.2 hectares. Artemisia is an undemanding plant which requires little chemical pest control. That makes it especially suitable as a medical plant. Pharmaceutical producers convert the natural product into derivatives that are more easily taken up by the body, and then combine them with other drugs to prevent the malaria parasite from developing resistance.

## BIOTECHNOLOGICAL PRODUCTION: THE FIRST APPLICATION OF SYNTHETIC BIOLOGY

In 2006 Jay Keasling, a synthetic biologist from the University of California, Berkeley, and his team engineered yeast to produce artemisinic acid, a precursor of artemisinin (Ro et al., 2006). Supported by a US$ 42.5 million grant from the Bill & Melinda Gates Foundation, the researchers engineered the metabolic pathway, which comprised twelve new synthetic genetic parts. In April 2013 the Paris-based pharmaceutical company Sanofi launched a new production facility in Italy. Sanofi expects to produce about 35 tons of artemisinin in 2013, and 50–60 tons in 2014. This amount will meet about one third of the global need. Keasling envisions that in the future the entire market can be satisfied using the semi-synthetic process. He agrees that gradual introduction is necessary in order to avoid driving conventional producers out of business – at least "until we have enough installed sufficient capacity to take over the entire world supply" (Peplow, 2006).




Westfall P J et al. PNAS 2012;109:655-656

**Fig. 2:** Artemisinin Production

## MULTIDIMENSIONAL ETHICAL CONFLICTS

At first glance, the ethical evaluation of artificial artemisinin production looks like a straightforward classical risk-benefit evaluation:

The main benefits of producing artemisinin in a semi-synthetic way are its expected lower production costs and the stable supply that will ensue. Lower production costs are an important benefit if the decrease in costs is to be passed on to the customers. For many patients malaria drugs are unaffordable and a lower price could enable them to access the treatments. The second main benefit of biotechnological artemisinin production is a stable supply: production would become independent of crop failure and independent of the unstable market of *Artemisia annua* production. In addition, even though *Artemisia annua* is

grown on sandy and poor soils (Dalrymple, 2012) it might be in competition with other important land uses.

The main biosafety risk is an unintended release of the engineered yeast that is employed for the artemisinic acid production. In traditional genetic engineering a potential harm to health and to the environment is predicted on the basis of the potential risks of the parental organisms. As noted earlier, in the case of synthetic biology the number of parental organisms and introduced genes rises significantly and the prediction of potential risks becomes prone to a high degree of uncertainty. That is also true for the artificial metabolic artemisinic acid pathway in which a high number of bacterial, yeast, and wormwood genes are pieced together. In fermenter production the risk of unintended release is relatively low. Therefore, in the light of the potential benefits and the relatively low probability of accidental release, the potential risks associated with biotechnological artemisinin production are often judged as ethically acceptable.

This assessment changes, however, when one looks at the case in more detail. In recent years farmers planted tens of thousands of additional hectares of *Artemisia annua.* In 2007 the artemisinin market became saturated with supply and the prices of natural artemisinin crashed. At present artemisinin costs about US$ 400 per kilogram and the semi-synthetic version is unlikely to be much cheaper. In addition, the prospect of synthetic artemisinin production further destabilized the market for natural Artemisia and has therefore had a negative influence on the security of supply. However, in the long run there should be sufficient production capacity for semi-synthetic artemisinin to meet the world’s demand. With the benefits becoming uncertain new ethical problems arise: Artemisia producers will lose a source of income and only a small number of companies will reap the benefits of the genetic resources. Local production and extraction of *Artemisia annua* in regions where malaria is prevalent will shift to the main production sites of Western pharmaceutical companies. As in the historic example of rubber in Malaysia, a synthetic production of otherwise naturally derived molecules is likely to have huge effects on trade, particularly in the developing countries. Whilst one might assume that most of the benefits from this anti-malarial drug will become available in developing countries, in which malaria is endemic and in which low prizes could make the biggest difference, one may need to conclude that the Western pharmaceutical market, driven by developments in synthetic biology, may again replace local production, depriving local populations in developing countries of their livelihoods.

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# THE CASE OF NANOTECHNOLOGY

Nanotechnology is a relatively new technology that aims to manipulate matter at the nanoscale level. Although nanoparticles were used in medieval times for stained glass windows, the beginning of the nanotechnology field is often traced back to a talk by Richard Feynman, "There is plenty of room at the bottom," (1960, p. 22–36) in which he discussed "the problem of manipulating and controlling things on a small scale". However, the manipulation of matter at the nanoscale level in the manner envisaged by Feynman only began in 1981 with the development of the scanning tunnelling microscope.

## FRAMING THE FIELD

Nanotechnology is commonly seen as an enabling technology, that is, it can enhance other technologies. One example of this is the role that advances in nanoelectronics have played in the development of computer technology over recent years. Nanoelectronics has contributed to the greater processing speed and particularly the expansion of memory capacity of current computers and to the development of hand-held devices. According to the nano.org.uk website, "in simple terms, nanotechnology can be defined as 'engineering at a very small scale'". A nanometre is $10^{-9}$ of a meter, that is, one billionth of a meter. (A human hair is about 60,000 nanometers in diameter.) Nanotechnology is most often explained in terms of size and is concerned with matter in the 1–100 nanometer range in which new properties emerge. The science.org.au website explains it like this:

> "Materials behave very differently at scales below about 100 nanometres,... Desirable properties of nanomaterials can be exploited for exciting applications such as improved chemical reactivity, ability to absorb or reflect light, and differences in material strength, flexibility or response to rises in temperature or pressure. In addition, we can engineer or pattern materials at the nanoscale, such as in advanced silicon chips or nanosensors, to gain amazing enhancements in desired properties."
> (Australian Academy of Science, 2012, p. 2)

Much of the work, and ethical discussion, in nanotechnology concerns nanoparticles and the related carbon nanotubes (fullerene-like substances – see Fig. 2). These particles and nanotubes have at least one dimension of 100nm or less and come in a variety of shapes and sizes. For example, Buckyballs (Buckmeisterfullerines) are spherical while other nanotubes are threadlike and of different lengths. These particles have a variety of uses and their use has led to much of the discussion of risk within the nanotechnology field.

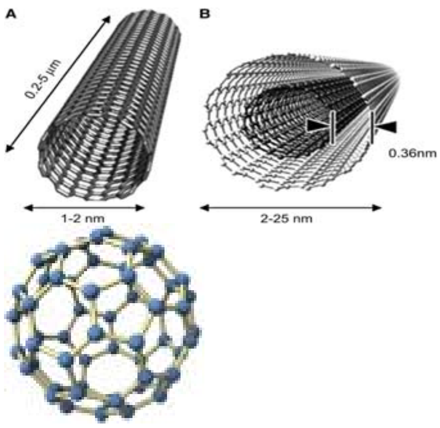


**Fig. 2:** Top: Nanotubes; Bottom: Buckmeisterfullerines

The nanotechnology field outlined above is not quite the nanotechnology field that received most attention several decades ago after the publication in 1986 of Eric Drexler's book

“Engines of Creation: the Coming Era of Nanotechnology”. His view, which was more visionary, became sidelined to some extent, but in a recent book, “Radical Abundance: How a Revolution in Nanotechnology will Change Civilisation” (Drexler, 2013), he has attempted to resurrect it. Sometimes called molecular manufacturing, Drexler now calls it Atomically Precise Manufacturing (APM). APM, he believes, has the potential to lead to vast improvements in products, in their cost, range and performance (Drexler, 2013, *A necessary prelude*[9]). Further, he predicts that very small, even perhaps desktop sized machines will produce some of these products (ibid., chapter 11). While this form of nanotechnology will be mentioned from time to time, the focus of this case study will be on the nanotechnology outlined at the beginning, namely an enabling technology that uses engineering at the very small scale.

Two issues help frame the field of nanoethics although they are also relevant to other fields of applied ethics. One issue relates to the way in which nanotechnology has been portrayed. It has been claimed to be ‘new’ when funding is sought for research and development but less ‘new’ or ‘novel’ when questions are raised about its safety (Sparrow, 2007). The second issue concerns comparisons that are often drawn with genetically modified organisms (GMOs), and talk of the ‘GMO disaster’. The phrase ‘GMO disaster’ refers to the fact that GMO foods have not been accepted well, particularly in Europe, and that there has been resistance to them around the world. It is feared that the same could happen with nanotechnology. There is a fear that much research may be done and many products may be developed, but then these may be rejected by the public. Hence, the nanotechnology community has been proactive in trying to educate the public regarding the benefits of nanotechnology and in trying to allay public anxiety. Ethicists have been enlisted to help with this process. The question now arises whether nanoethics is really assessing the moral issues in nanotechnology or whether it is instead a servant to the technology. The ‘GMO disaster’ can only be called a ‘disaster’ *if* the technology was safe, not otherwise. If it is not safe or if the evidence that it is safe is not strong, then the public backlash was justified and was certainly not a ‘disaster’.

## THE CURRENT MAIN APPLICATION OF NANOTECHNOLOGY

Because nanotechnology is an enabling technology, it has applications in a wide variety of fields including health, materials, electronics, energy, food and agriculture. The following graph shows the approximate uses in 2006, 2011 and 2013:

9 Kindle version of book has no page numbers.

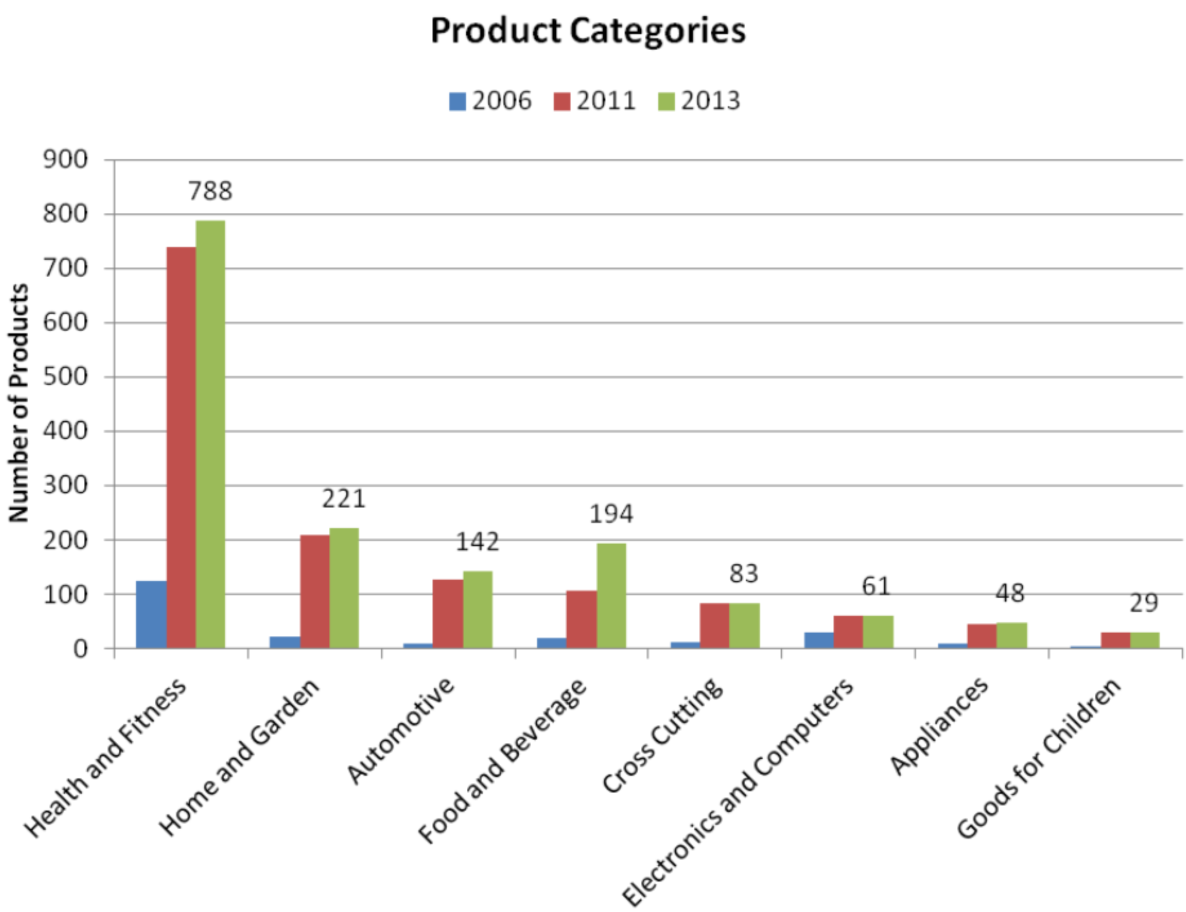


**Fig. 3:** Product Categories for Nanotechnology
http://www.nanotechproject.org/cpi/about/analysis, accessed 14 January 2014

**Table 5:** Existing and envisioned applications of nanotechnology

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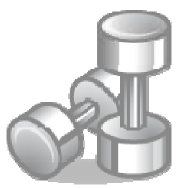
<td></td>
<td>Health and Fitness
<ul>
<li>Super ‘muscles’: Carbon nanotubes infused with paraffin wax have been created that contract and release when heated by an electric pulse or light. These have the potential to lift weights up to 200 times heavier than natural muscle. Though not able to be used to replace human muscle yet, the proclaimed uses include “robots, catheters for minimally invasive surgery, micromotors, mixers for microfluidic circuits, tunable optical systems, microvalves, positioners and even toys” (UT Dallas, 2012).</li>
<li>Appetite stimulation: Nano crystal particles can be added to food or drugs to promote appetite in people with anorexia, AIDS etc. (Megace, not dated).</li>
<li>Antibacterial coating for hospitals: ‘Nanopool’, a spray-on glass, is a form of non-thick glass coating which repels water and dirt. It is being used in some hospitals where it has been shown to reduce the bacterial load on children’s toys and such like. (Nanopool 2010).</li>
<li>Water filtration: The ultrafiltration of water using a nanosize alumina filter “which attracts and retains sub-micron and nanosize particles” can sterilise water, with one possible application being the purification of water for drinking in the developing world. (Nanotechnology Now, 2012).</li>
</ul>
</td>
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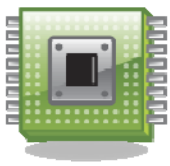
| | |
|---|---|
| | • *Sporting goods*: Tennis rackets, golf clubs etc. use nanotubes to increase strength while decreasing weight of the given piece of sporting equipment (ibid.). |
|  | **Food and Beverages**<br><br>• *Nanotexturing*: Nanotextured foods have their textures altered, making them more palatable while decreasing the need for unhealthy ingredients like fat. Examples include ice-cream, mayonnaise and similar products. It is not clear if any such products are on the market yet, but in 2012 they were thought to be close (FAO/WHO, 2010, p. 10).<br>• *Nanoencapsulated additive delivery systems*. Desired ingredients, such as preservatives, or nutritional or probiotic supplements, are encapsulated in a nano-enclosure allowing for increases in flavour and control. Nano-enscapsulation is used to alter the fat/water solubility of micronutrients such as vitamin C and vitamin A. (FAO/WHO, 2010, pp. 11–12).<br>• *Smart food packaging*: Food packaging incorporating nanoparticle-reinforced materials, which are stronger and lighter than other materials, can improve the shelf-life of the food, and smart packaging incorporating nano-sensors can provide information on the quality of the food contained in the packaging. (FAO/WHO, 2010, p. 15). |
|  | **Electronics and computing**<br><br>• *Ultra low power semiconductors*: These semiconductors can be used as communication chips for the so-called 'internet of things', in which every object in the world has its own IP address. Nanoscale microchips can transmit ultra-wide radio wave pulses that require only 37 5 pJ (picojoule) of energy to receive one bit of information (Johnson 2013). |

## AREAS OF ETHICAL CONCERN

### HEALTH RISKS

One of the main ethical concerns in nanotechnology is the possibility of risks to human health. Generally, the worry is not so much that it is *known* that particular nanoparticles pose health (or environmental) risks, but rather that not enough is known yet to enable us to understand their effects properly. Nanoscale particles, as previously mentioned, have properties that are different from properties of larger particles of the same material, due in large part to their greater surface area relative to size (i.e., smaller articles have a higher surface area to volume ratio than larger particles). According to Seaton et al., "[s]urface area is the metric driving the pro-inflammatory effects." (Seaton et al., 2010, S123). However, their effects in the body are not yet very well understood.

Concerns about health risks have led to calls for the precautionary principle to be applied and for products containing nanoparticles to be withdrawn from the market as well as

observing a moratorium on further development until more research into safety has been undertaken (FoE 2007). One concern, to be explored further in the *Specific case* section, relates to products such as cosmetics and sunscreens that are applied to the skin, and another concern relates to particles that are used for targeted drug delivery and diagnostic purposes. Concerns have been raised, too, that thread-like nano-particles that can be inhaled might have the same effects as asbestos and lead to serious lung disease (Bell, no date). A House of Lords report in Great Britain focused on the use of nanotechnologies in food, which is also causing some concern. According to this report, the potential applications in the food industry include "creating foods with unaltered taste but lower fat or sugar levels, or improved packaging that keeps food fresher for longer or tells consumers if the food inside is spoiled" (House of Lords, 2010, p. 5). The report highlights the fact that little is known of the potential dangers of the technology because of the lack of research in the area.

## DISTRIBUTIVE JUSTICE

Another ethical concern is that nanotechnology will lead to an increase in the disparity between the developed world and the developing world, with the term "nanodivide" being frequently used. Most of the products using nanotechnology are likely to be of benefit to those who are already well-off given their purchasing power. These harms to the developing world are relative: the poorer parts will become relatively poorer simply because the richer parts will become richer in absolute terms.

Another aspect of the nanodivide concern is that products will be developed and produced in rich countries and that these will replace natural products currently produced in poorer countries. This concern was raised by the ETC group (Action group on Erosion, Technology and Concentration, 2004) in relation to synthetic rubber production that would replace natural rubber (this concern also has been outlined in the synthetic biology case study). The creation of a nanodivide is not seen as a risk by all. Some, for example Peterson and Heller (2007), argue that nanotechnology will in fact confer extensive benefits on developing countries by producing much-needed products such as efficient water purifiers. Others, for example Schummer (2007), have cause to doubt this. One argument is that currently available technologies that could help alleviate many of the problems are not being used, so why would nanotechnologies be any different?

## PRIVACY AND AUTONOMY

New monitoring and surveillance technologies, enabled by nanotechnology, pose threats to personal privacy. There is the potential for harm through loss of autonomy. Technologies, such as certain computer technologies, are already threatening privacy and these new nano-enhanced monitoring and surveillance technologies, that can improve computer memory and processing speed, together with more sensitive sensing devices, will almost certainly exacerbate the situation. These computers and sensors will become even smaller making their detection more difficult.

## MILITARY USES

A further ethical issue relates to the military use of nanotechnology. Three (potential) uses of nanotechnology in warfare will be mentioned here. The first is nanotechnology and

chemical weapons. While many of the developments in nano-enabled drug delivery will be medically beneficial, there is the potential for these developments to be used in the delivery of chemical or biological weapons, for example chemical agents that target specific parts of the body. These developments could enable more effective use of lesser amounts of the agents. It is a concern that the weapons thus produced may not be covered by current regulations (Balali-Mood et al., 2008).

A second example is the development of autonomous weapons, that is, weapons that can find targets and make decisions about killing or destroying them without human intervention. They may take over the role of killing, including deciding who to kill. This raises serious ethical questions about the responsibility for attacks and also necessitates further examination of what constitutes a just war and defensible actions within such a war. These weapons are not purely the result of research in nanotechnology, as advances in nanoelectronics have helped enable the computer power necessary for these weapons to respond to their environments in real time and therefore have at least some autonomy.

Finally, research into human enhancement raises many ethical issues. However, how it will change warfare is perhaps less clear. For example, the practice of attaching carbon nanotubes to specific neurons in order to enhance their natural signal-processing capabilities could be used to enhance memory retrieval. This would certainly give those using the technology to enhance their senses an advantage. If aims to enable a human to accomplish what three or more do now were to be realised, soldiers might be able to operate for longer under stress and for longer without sleep than they can now. This would be an advantage but would probably not change warfare itself much, although it could widen the nanodivide still further. An interesting point to consider is what might happen if this kind of enhancement becomes part of an arms race. Human enhancement also has implications for our views on what it is to be human.

## ENVIRONMENTAL RISKS

Research by various military groups to explore the merging of technology with insects in order to create miniature cyborgs for military purposes is an area in which concerns about military developments and environmental concerns merge. It is unclear what effect, if any, this would have on the native insect population. It is, however, currently difficult to find reliable literature on this.

In health, nanotechnology has potential environmental benefits as well as risks, and in fact much of the literature on nanotechnology and the environment describes the benefits. Proposed benefits include purifying polluted water, cleaning up polluted land, more efficient solar cells and developing sensing devices and technologies to detect pollution at much more refined levels than is currently possible.

The environmental risks discussed to date have not so much focused on nature, but rather on risks to the health of people who come into contact with the particles through, for instance, modified plants. The following two examples of nanoparticle concerns come from the sectors of agriculture and aquaculture.

Firstly, concerns about manufactured nanoparticles and manufactured nanomaterial (MNM) are being raised within the agricultural sector. Because its effect on the environment and health is not yet clear, certain uses of MNM have been called into question. Evidence suggests that nanoparticles enter the food chain through food produced on soil containing MNM and, while they can enter the soil in various ways, a common way in some countries is through the use of biosolids (a by-product of the sewage treatment processes) used as fertilizers. Research has shown that in soybeans MNM accumulates in the leaves and beans and thus poses a potential risk to the food supply and to human health (Priester et al., 2012). Secondly, in aquaculture this issue also arises in the use of nanoparticles for vaccine delivery in fish farming. While such delivery appears to be useful for fish farming, fears have been expressed about the effects of these particles on the environment more generally (Myhr and Myskja, 2011). The ethical discourse summarized here can be ascribed to the first two categories of RRI – ethical acceptability and sustainability – in the following manner:

**Table 6**: Areas of ethical concern in nanotechnology in the light of RRI

| | |
|---|---|
| • Health risks (nanoparticles)<br>• Misuse / dual use (privacy, autonomy risk, terrorist misuse)<br>• Distributive justice (nanodivide)<br>• Challenge to the concept of life (human enhancement, cyborgs) | **Ethical acceptability** |
| • Interference with nature (nanoparticles, cyborg-insects)<br>• Environmental risks (nanoparticles) | **Sustainability** |

## SPECIFIC CASE EXAMPLE: NANOPARTICLES IN SUNSCREENS

A common use of nanoparticles is in sunscreens. Given the importance of sunscreens and concerns about the toxicity of nanoparticles, the use of nanoparticles in the production of sunscreens has generated considerable debate. This is particularly so in Australia, which has the highest skin cancer incidence rate in the world. Approximately two thirds of Australians will be diagnosed with skin cancer before the age of 70 (Australian Government 2013). As a result, the use of sunscreens is actively advocated by governments and medical groups. The safety of these products is therefore paramount.

The purpose of sunscreens is to prevent damage to the skin from the sun by absorbing or scattering ultraviolet (UV) radiation. The active ingredients in sunscreens can include particles of metal oxides such as Titanium Dioxide or Zinc Oxide, or molecules such as Octyl Methoxycinnamate, 4-Methylbenzylidine Camphor, or Butyl Methoxydibenzoylmethane. Typical sunscreens using these ingredients can be easily seen when applied because of their creamy appearance on the skin (CSIRO, not dated).

Zinc oxide (ZnO) and titanium dioxide (TiO2) nanoparticles (NPs) are currently being used in sunscreens, for two reasons. Firstly, these nanoparticles have a broader range of UV protection than their molecular counterparts in older sunscreens and, secondly, sunscreens that contain these nanoparticles of metal oxides are transparent and are not creamy on the skin.

## HEALTH RISKS

The main concern about these new sunscreens is whether or not the nanoparticles can penetrate the skin and cause damage. One concern is that nanoparticles might be able to pass through the skin and lodge in various parts of the body where they could cause harm. Faunce et. al. for example, suggest that the evidence so far is inconclusive regarding whether or not titanium dioxide and zinc oxide, both used in sunscreens and known to be harmful to cells, can penetrate the skin (Faunce et. al. 2008). This concern is exacerbated by the fact that using sunscreens is not an option in many parts of the world. The choice is between using sunscreens that may cause harm and risking acquiring skin cancer. The argument, it must be emphasized, is not so much that the nanoparticles are harmful, but rather that it is not clear yet that they are not and that therefore the precautionary principle should be applied. The strongest advocates for this approach are Friends of the Earth (FoE) and, in a recent report, they cite various studies that suggest dangers associated with these sunscreens (FoE, 2012).

Another recent report, by the Australian Government Therapeutic Goods Administration, reviews the research literature on nanoparticles in sunscreens and argues that the evidence suggests that these particles do not penetrate the skin beyond the *stratum corneum* and therefore are unlikely to pose any risk (Australian Commonwealth, 2013).

Two arguments need to be explored when considering the ethical issues arising from the manufacture of sunscreens containing nanoparticles. One argument is that sunscreens are vital if the risk of skin cancer is to be minimised and that people appear to prefer sunscreens that are transparent. If people are more likely to use sunscreens if they are transparent, then, assuming the risk from nanoparticles was very slight, it would seem better to produce them than not. On the other hand, it can plausibly be argued that, because effective alternatives exist, there is no need to use nanoparticles in sunscreens. Therefore, even if the risk is only slight, the precautionary principle should be applied until they are shown conclusively to be safe. If the only advantage is aesthetic, namely no creamy substance visible on the skin, it would seem that any risk is not worth taking.

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# THE CASE OF INFORMATION AND COMMUNICATIONS TECHNOLOGY (ICT)

The field of Information and Communications Technology (ICT) is extremely broad and has applications in, and implications for, almost every area of human activity and enterprise. In most cases ICT involves the integration of activity and data from a number of different sources utilizing a range of technologies. The effect is to blur boundaries between technologies and by implication raise many important ethical issues. ICT applications, either by themselves or in conjunction with other technologies, cannot only challenge existing social, cultural and ethical norms but are frequently transformative in nature, having long lasting, possibly irreversible consequences for human society and the direction of its development. It is therefore essential that the ethical acceptability and sustainability of ICT applications is carefully considered. As already mentioned the societal desirability of ICT applications will be discussed in a later document.

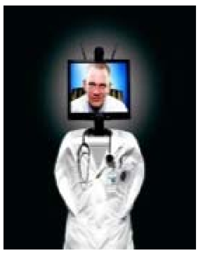
## FRAMING THE FIELD

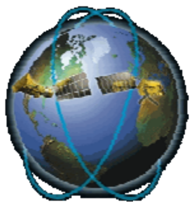
The history of ICT and its development has been extremely rapid. Although one might argue that the abacus, invented over 3,500 years ago, was the first ICT application, modern ICT can be considered to have started with the production of the first commercial computer in 1952. The invention of the Internet followed 17 years later in 1969, which made the development of email possible. The first personal computers and Internet access through a modem were achieved in the early 1970s. After the World Wide Web was launched in the early 1990s, Internet shopping became possible in 1995, Google's search engine was launched in 1998 and social networking started in 2004. One of the most powerful applications in bringing the Internet into everyday use for society, which has dramatically increased the flow of data, has been the "smartphone" in the form of the iPhone introduced by Apple in 2007.

The speed at which these innovations have progressed has been truly remarkable with each development creating the ability to generate, communicate, store and manipulate increasingly vast quantities of data. In 1995 there were just 16 million Internet users. Today there are over 2.7 billion or almost 40% of every man, woman and child on the planet. In more recent years, the amount of data that the Internet handles has been increasing more rapidly every year and it is estimated that between 2.5 and 5.0 quintillion bytes of data are now generated every day (IBM, not dated). Increasingly more and more of this growth is due to the use of social media and smartphone applications.

The term "ICT", as it is now understood, encompasses areas such as telephone, broadcast media and all types of audio and video processing and transmission (FOLDOC, 2010), and involves the integration of telephone lines, computers, software, audio systems and video systems, all of which allow the storage and manipulation of data. Furthermore, ICT is inherently linked to a wide variety of sensory systems and technological artefacts and could also be considered to encompass aspects of robotics, particularly in relation to service and companion robotics and even autonomous transport systems.

**Table 7:** Existing and envisioned applications of ICT

| | |
|---|---|
|  | **Augmentation (Therapeutic and non-therapeutic human implants)**<br>• Neurostimulation / suppression<br>• Brain-computer interface<br>• Vision and hearing implants<br>• Memory enhancement<br>• Cognitive enhancement<br>• Mood altering<br>• Pleasure stimulation<br>• MEMS – remote sensor signalling of medical conditions<br>• Data storage<br>• ID and tracking microchips (RFIDs)<br>• Muscle enhancement<br>• Cyborgs and human telekinetics |
|  | **Biometrics**<br>• Facial recognition<br>• Thermal recognition<br>• Iris scanning<br>• Retinal scanning<br>• Fingerprint recognition<br>• Vein recognition<br>• Gait recognition<br>• Voice recognition<br>• Multiple biometrics |
|  | **Telemedicine**<br>• Remote consultation and diagnosis<br>• Remote testing (e.g. blood, breath)<br>• Remote surgery<br>• Remote rehabilitation (training and assessment) |
|  | **Smart Buildings**<br>• Security<br>• Energy efficiency<br>• Occupant monitoring for location, movement, health and well-being? |

| | |
|---|---|
|  | **Service and Socially Assistive Robotics**<br>• Assistive robots for elderly and disabled people<br>• Companion robots<br>• Domestic robots for household tasks<br>• Robotic/Automatic transport<br>• Healthcare robotics |
|  | **Information and data access**<br>• Internet and web access<br>• Automatic diary/reminders |
|  | **Ubiquitous communication and control technologies**<br>• Smartphone and GPS applications for communication, identification, monitoring, tracking, data collection and access |

ICT, together with, and frequently integrated with, other leading edge technologies is now a core element of the research and innovation agenda of the modern world. It is seen as a vital vehicle for stimulating economic activity and growth not only as an enabling technology but also as a constant source of new and innovative applications to benefit society, develop competitiveness and improve productivity.

A further important aspect of more recent ICT applications is the ease with which they permit collection, storage and analysis of enormous quantities of personal and other data; including

- data on shopping from loyalty cards,
- data generated from search engines indicating the interests of users, their location, and their activities,
- personal data gathered from Internet shopping and browsing and
- personal data gathered from the use of smartphone and tablet applications.

These data are very valuable to companies and their advertisers, enabling manufacturing, advertising and the development of business models to be targeted not only to particular market sectors and groups but also to specific individuals. Such large amounts of data are also a valuable resource to the public and private research community. Internet websites, search engines, online data sources and smartphone apps also enable providers to sell advertising space at premium prices. Global online advertising is growing rapidly and is

estimated to be worth around US$ 72 billion per year by 2015 (Global Industry Analysts Inc., 2013).

ICT has been a central element in the development of almost all aspects of modern life over the past 20–30 years, particularly in the developed world and in more recent years increasingly in the developing world. This has resulted in applications and innovations that have produced technological advances which have greatly benefited society and caused exceptional economic growth. However, these innovations have also challenged traditional ways of living and values.

For instance, ICT is anticipated to have an increasing role in biomedical applications and healthcare that involve some form of augmentation of the human body. In many cases this will be seeking to restore the body to its normal functionality following some form of disease or disability-causing event. It could involve implants to link muscles to nerves to move artificial limbs, to facilitate speech, vision or hearing, to reduce pain, relieve depression or to enhance memory in case of, for example, Alzheimer’s disease. It is even possible to use micro-sensor implants (MEMS) to inform doctors remotely of a patient’s medical condition. All such applications and more are currently being researched or developed and many do raise important ethical issues (Nsanze, 2005; EthicBots Consortium, 2008).

## AREAS OF ETHICAL CONCERN

In 1997 the European Commission published an important report from a High Level Expert Group (HLEG Report, 1997) which represented the first serious European attempt to formulate a social discourse about the information society. The HLEG asked what it was that distinguished the “information society” from other societal models. It concluded that a key element of the information society concerns the relationship between the human factor and the technological factor and that such a relationship should be governed by a social integrationist approach to ICT and science, as opposed to a technological deterministic one.

“The social integrationist vision that the High Level Expert Group espouses explicitly rejects the notion of technology as an exogenous variable to which society and individuals, whether at work or in the home, must adapt. Instead it puts the emphasis on technology as a social process.” (HLEG Report, 1997)

This means that technology must serve the people for whom it is designed rather than require that people adapt to technologies. Ethical challenges of ICT can be considered as risks across a wide range of areas including health, privacy, concerns about distributive justice, and challenges to human well-being through isolation or confusion about the nature of the self (see Mordini and De Hert, 2010).

### HEALTH RISKS

ICT per se is not generally considered to give rise to significant risks to physical health. There are still, however, ongoing discussions about the potential health risks of electromagnetic radiation and, although there is currently no hard evidence of significant health impacts, the dramatic growth of wireless technology does give some people cause for concern. The possibility of ICT implants in the human body does present some possible risk in relation to

the implantation procedure itself, mode of operation and possible rejection by the body. However, none of these potential risks have to date been quantified. They do, of course, raise an important question about whether any such implant, wherever in the human body it is located, constitutes a clinical process which would require the development and application process to be subject to clinical trial. An alternative approach may be to use induction-based devices which “read” neural electrical signals from outside the body and respond accordingly. However, there is significantly greater risk of specific applications of, or reliance on, ICT, giving rise to psychological problems, mental disorders, addictions, de-socialisation or antisocial behaviours or disorders.

## PRIVACY AND DATA PROTECTION

In Europe, the use of ICT is heavily regulated in order to protect citizens from a breach of confidentiality or privacy by anyone who has access to or uses an individual’s data. The primary legal expression of this provision in Europe is through the Directive on the protection of individuals in regard to processing and free movement of their personal data (Directive 95/46/EC), which has been translated into law in all the European member States. This legal document is currently approaching the end of an extensive review process and may shortly emerge in the form of a European Regulation. However, the extent of the data protection issues and the challenge to protect citizens can be illustrated with the example of Facebook. These challenges are global and not restricted to Europe. The Facebook application (‘app’) on a smartphone requests permission to do the following:

- Automatic provision of location data (e.g. via GSM (Global System for Mobile Communications) or GPS (Global Positioning System))
- Tracking
- Access to phone usage records
- Ability to read, save and erase call log data
- Access to personal contact details including times, dates, type and number of contacts to specific individuals
- Ability to modify and/or delete storage data and contact data
- Access to smartphone recording and video functions and ability to record, photograph and video-record without requesting further permission
- Directly dial numbers from smartphone without further permission
- Download files without notifying user
- Identify and read information on other connected network devices

Facebook is by no means the only smartphone app to make these kinds of requests for access to personal data. Google Maps, for example, has recently provided an upgraded version, but in order to install and use the upgrade the user has to give Google maps permission to “Read your Contacts” (see Box 1).

> BOX 2
>
> Google Maps App. requests permission to **Read your Contacts**
>
> “Allows the app to read data about your contacts stored on your phone, including the frequency with which you’ve called, emailed or communicated in other ways with specific individuals. This permission allows apps to save your contact data without your knowledge.”

This raises many issues in relation to privacy and data protection. A key concern in relation to the data requests from smartphone apps, and

indeed from some of the equivalent software for desktop and laptop personal computers, is that there is very little transparency about the true nature of the access they are requesting including the nature of the data they are asking for, the mechanisms and circumstances under which they will access it, why they need such access and whether it is necessary for use of the application. The information provided in Box 1 can only be found by probing two levels below the initial request to install the upgrade. This is also true for Facebook and for many other requests. In some cases the true implications of granting the programme access to one's personal data can only be understood by carefully reading the whole of the app's Terms and Conditions. Most people have neither the time nor inclination to do so. This is not surprising when Facebook's Terms and Conditions run to over 14,000 words and those of other sites such as Twitter and LinkedIn have similarly dense terms and conditions.

Such a situation is hardly transparent for the potential user and the great majority of people are likely to accept the access request together with the terms and conditions without being aware of the implications. However, in most cases they are granting the application's owner rights over their personal data that are stored on or pass through the site, including, in most cases, the ability to commercialise or relicense such data and information. Users of LinkedIn, for example, grant its owners extremely broad rights in relation to the information they include on the site (see Box 2).

It is probably true that most high profile organisations, despite having been granted such wide-ranging rights to access and use of personal data, will nevertheless make some effort to comply with either national or international legislation where this exists and would not wish to appear exploitative or be seen as blatantly breaching people's privacy. However there is no doubt that there are many other apps and programmes that have requested and been granted wide-ranging access to and use of personal data which could misuse such data access.

BOX 3:

**Extract from LinkedIn Terms and Conditions**

"[Y]ou grant LinkedIn a nonexclusive, irrevocable, worldwide, perpetual, unlimited, assignable, sublicenseable, fully paid up and royalty-free right to us to copy, prepare derivative works of, improve, distribute, publish, remove, retain, add, process, analyze, use and commercialize, in any way now known or in the future discovered, any information you provide, directly or indirectly to LinkedIn, including, but not limited to, any user generated content, ideas, concepts, techniques and/or data to the services, you submit to LinkedIn, without any further consent, notice and/or compensation to you or to any third parties".

With the storage, processing and data mining capabilities of modern technologies growing at a breath-taking pace, privacy and data protection can be seen as constitutive values that safeguard participation and association in a free society. Such protection will remain the main ethical issue of ICT in the foreseeable future.

## DISTRIBUTIVE JUSTICE

Notwithstanding the potential for data misuse and invasions of privacy, ICT has revolutionised the world in many positive ways. One just needs to remind oneself of the work of a secretary using a typewriter to produce a profit and loss statement for a company: every time a figure had to be corrected, the typing started again, as did the manual

calculation of the sums. The introduction of the word processor has eliminated this problem to such an extent that today, only having access to a typewriter would severely limit one's ability to function effectively in the workplace. As new technological applications become the norm, not having access to ICT can therefore be a major disadvantage to any person, as part of work or leisure and can effectively bar them from many of the interactions and requirements of everyday society. Right of access to the technology therefore becomes an issue of distributive justice.

## ISOLATION and EXCLUSION

ICT is increasingly providing technological solutions to aspects of life that previously would have been dealt with through face-to-face interactions. Some of these developments can be positive. For instance, if one lives 25 km from the nearest city, but has high-speed broadband Internet access, one probably welcomes the possibility to submit applications for new waste bins online rather than having to hand over a form to a public official. However, if one is 85 and the town hall is next door, this may be different.

In Europe, much governmental and public bureaucracy now requires individuals to engage with public service entities online. Citizens are required to apply online for various public permits, licenses and even social security benefits, and also to complete tax returns online. In the UK, even farmers are required to make their stock returns online. Doctors' surgeries encourage patients to log on to make or change appointments. While these changes can increase efficiency and make life easier for many, for those who are unfamiliar with or have no way to utilise the technology, they can present very serious obstacles to accessing public services or being an active member of society. On the one hand, those who are disadvantaged may become increasingly dependent on others to support them. However, on the other hand, increased reliance on remote technological solutions to bureaucratic and other activities can severely reduce our day-to-day contact with other people.

Hence, while there are many benefits that arise from the convenience and connectedness that ICT affords, there are concerns that have to be considered. It has been suggested (Mordini et al., 2009) that ICT does not enrich our human characteristics but rather replaces them by unnatural, technological characteristics, which are determined by scientists, industry and the market. It has also been argued that ICT does not multiply or enrich relationships among humans, but that ICT reduces the rich complexity of human contact to purely technical connections with distant or virtual contacts, leading to isolation and the exclusion of some.

## UNDERSTANDING OF THE SELF

ICT and other technological interventions related to the augmentation of human facilities, be they physical, mental or emotional, have the potential to raise fundamental questions about the nature of humanity. At what point do changes to normal human anatomy and physiology begin to impinge on what it means to be human? There are many augmentation developments in the form of implants that have the ability not only to restore lost function but also to enhance normative functionality significantly or enable activities that are not within normal human capabilities. One particular example is that of the cybernetic organism (cyborg), in its simplest definition, a being with both organic and artificial parts but

frequently used to refer to self-regulating human-machine systems with enhanced capabilities. Work by Prof. Kevin Warwick has shown that it is not only possible to have wireless control of machines through implants directly connected to the human nervous system, but he has also demonstrated that it is possible to connect two human nervous systems wirelessly such that one person can control the movements of another (Warwick, 2002). While such possibilities are truly fascinating, they could well lead to detrimental changes in the nature of human self-understanding and human interaction. Indeed, as our identity and self-awareness is to a great extent bound up in the way in which we interact with others, the development and use of empathetic robots, whether in a service role and/or as a companion, may fundamentally affect our understanding of ourselves and others particularly in relation to machines or programmes with which we can interact at an emotional level.

## MISUSE

The broad range of possibilities opened up by developments in ICT, while providing tremendous beneficial possibilities, also has the potential for misuse, either intentional or unintentional. This may be as a result of a lack of appropriate regulation, or indeed out-of-date regulation. Once an ICT application has been identified as useful and feasible, it is almost always much quicker to develop and bring a product to market than it is to change existing legislation or develop new regulations to ensure beneficent rather than malfeasant outcomes. In Europe, this is already clearly seen in the outdated data protection Directive 95/63/EC. Although an important revision of this legislation is now (2014) almost complete, and may be implemented as a regulation, there are already new ways of collecting and using data that are unlikely to be covered by the new legislation.

Privacy issues related to applications for surveillance and tracking are also increasing challenges that can have great beneficial use for many but can also be easily misused by some. This could be an increasing problem as the cost of such technology becomes affordable to all. Many applications in telemedicine, biometrics and service robots may be (mis)used in ways that benefit professional or even family carers but raise ethical issues that impact on the human dignity and autonomy of the subject.

## SOCIETAL DEPENDENCE

ICT presents a very general risk to society as a whole simply because of its position at the heart of our societal and governmental infrastructures. We are becoming increasingly dependent on ICT to live our lives and to function as a society on a day-to-day basis. However, only very rarely does an individual ICT application exist in isolation from the rest of the ICT world. They all are increasingly part of a global network, or network of networks. Although there is always some built-in redundancy in such systems, any serious failure could have dramatic implications for society as a whole, whether that failure be through equipment breakdown, accidents, catastrophic natural events such as hurricanes, tidal waves, earthquakes etc., or the result of wars, sabotage or terrorist activities. There are few systems that would survive very long if faced with a catastrophic breakdown of a nation's electrical system. The more we depend on ICT and the more we rely on it to live our lives

both as societies and individuals, the more vulnerable we make ourselves to any failure of the technology.

## ENVIRONMENTAL AND SUSTAINABILITY RISKS

In addition to there being an energy cost to the utilisation of ICT applications including *inter alia* energy for developing infrastructure, hardware manufacture, equipment operation, data storage etc., the production of ICT hardware involves the use of almost every element in the periodic table, and in particular many elements which are in very short supply such as antimony, germanium, gallium, gold, silver, platinum, iridium, tantalum, ruthenium together with the "rare earth" metals such as yttrium, gadolinium, cerium, lanthanum and many others. As ICT products are increasingly becoming a significant component of waste, they must be recycled efficiently not only to avoid serious pollution but also to maintain a sustainable supply of components by recovering as many as possible of the elements which are essential, yet in short supply. However, ICT may also have important secondary effects on waste, pollution and the environment through the way in which it changes the activities and choices of individuals and society itself. For example, does online shopping and home delivery increase environmental pollution by transport, or does it reduce it by causing far fewer individuals to travel, sometimes great distances, to visit local shops or out-of-town shopping complexes? ICT applications themselves can of course facilitate and stimulate sustainable production and consumption across the entire economy (OECD, 2010).

The ethical discourse summarized above can be ascribed to the first two categories of RRI, ethical acceptability and sustainability, in the following manner:

**Table 8** Areas of ethical concern in ICT in the light of RRI

| | |
|---|---|
| • Health risks (electromagnetic radiation, failure or crashes in ICT equipment)<br>• Dual use (invasion of privacy and breaches in data protection)<br>• Misuse (violation of autonomy and self-determination through inadequate informed consent; privacy and data protection breaches)<br>• Distributive justice<br>• Societal dependence on ICT<br>• Challenge to the nature of humanity (physical, mental and emotional enhancement) | **Ethical acceptability** |
| • Environmental pollution by heavy metals in ICT hardware waste<br>• Increased energy consumption for ICT activity and data storage | **Sustainability** |

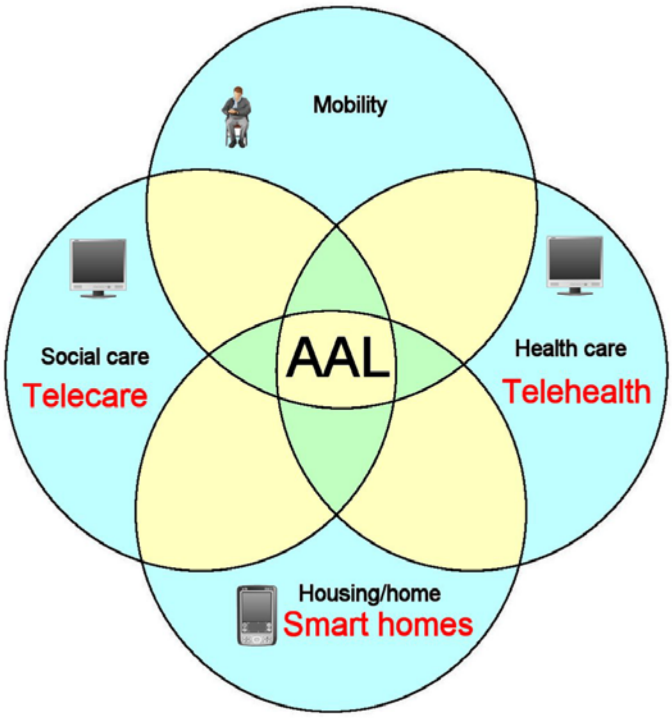
## SPECIFIC CASE EXAMPLE: AMBIENT ASSISTED LIVING

Assistive technologies for older citizens include affective computing; memory assistance; robotics (e.g. helper robots); ambient intelligence and sensors; ICT for physical and cognitive training; brain-computer interaction or more generally neuro-ICT interfacing; navigation systems; speech, sign and movement recognition; ICT for modelling and simulation of users and their interaction with devices; ICT for social networking; automatic language translation; collaborative creativity; alternative communication environments, and virtual worlds. Much important ethical analysis in this area has already been done by Mordini et al. (2009) through the EU funded project "Senior". One ICT application, which addresses a grand challenge in Europe (ageing societies) whilst simultaneously raising many ethical concerns, will be introduced in this section: the idea of Ambient Assisted Living (AAL).

Ambient Assisted Living refers to the use of intelligent, highly personalized, networked systems, devices and services that help elderly and disabled people to remain in their home with as much independence as possible for longer than otherwise would be possible. As defined by the AALIANCE Ambient Assisted Living Roadmap (Van Den Broek et al., 2010),

> "Ambient Assisted Living, AAL, refers to intelligent systems of assistance for a better, healthier and safer life in the preferred living environment and covers concepts, products and services that interlink and improve new technologies and the social environment. It aims at enhancing the quality of life (the physical, mental and social well-being) for everyone (with a focus on older persons) in all stages of their life. AAL can help older individuals to improve their quality of life, to stay healthier and to live longer, thus extending one's active and creative participation in the community."

**Fig. 5:** AAL is at the core of three main ICT clusters: tele-care, home tele-health and smart homes (adapted from Kubitschke and Cullen, 2010).




AAL technologies differ from more traditional forms of ICT-enabled assistive technologies as they rely on ambient intelligence systems, ubiquitous computing, ubiquitous communication and intelligent social user interface, and they can operate without direct input from the user.

"AAL" is an umbrella term including different kinds of ICT products and solutions that can be deployed in multiple physical spaces (room, home, car, workplace, shops, out-doors) and virtual spaces (e-shopping, gaming, chatting, searching for or planning activities) to meet the needs of users and, in this particular context, older or

disabled people, carers, home-care nurses, staff from community centres and emergency personnel.

Combined with the ever-expanding scope of wireless communications technology, ambient devices or sensors embedded within a building, a room, in clothing, on the pavement or on one's body require little or no knowledge of technology on the part of the individual. For instance, a sensor affixed to one's skin can collect and transmit data to one's doctor continuously; a sensor in a doorway can monitor one's passage from room to room; a load sensor in the floor might determine one's position or even weight (Mordini et al., 2009).

The range of technologies encompassed by the term "AAL" is wide and difficult to delineate; however, the following examples can be considered a representative sample: wearable, ambient and wellness measurement and monitoring technologies; service and socially assistive robots for activities of daily living and instrumental activities of daily living or rehabilitation; computer aided rehabilitation systems; machine learning and data mining tools for decision-making; sensor networks for pervasive care; robotics and automation in assistive living systems; ambient intelligence and pervasive computing; cognitive behaviour analysis and monitoring systems; computer-aided physical therapy and occupational therapy systems; telemedicine and biotechnology applications using pervasive computing.

Effective AAL technologies have to be:

- embedded (non-invasive or invisible devices, distributed throughout the environment or directly integrated into appliances or furniture),
- personalized (tailored to the user's needs),
- adaptive (responsive to the user and the user's environment),
- anticipatory (anticipating the user's desires as far as possible without conscious mediation),
- interconnected (the different devices and sensors are wirelessly connected to each other, forming a single system),
- context-aware (the system can recognize and react in an appropriate manner to the circumstance).
  (see Mordini et al., 2010)

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The adoption of AAL technology can result in an elderly person being heavily monitored by technology, but still being able to live at home rather than in a care home. Hence, ICT has the potential to develop an increasingly important assistive function for the elderly helping them to age well at home: enabling them to enjoy a healthier and higher quality of daily life for longer, assisted by technology, while maintaining a high degree of independence and yet enabling assistance to be provided as soon as a problem is detected.

At the same time, these technological changes will alter where, when, how and how often each individual interacts with ICT. Indeed, the ICT technologies at the core of AAL have been identified by projects such as the Safeguards in a World of Ambient Intelligence project (SWAMI 2009) or the Ethical Issues of Emerging ICT Applications project (ETICA 2010) as some of the emergent technologies that will most likely become an issue of ethical concern at the level of the European Union. The SWAMI project, for example, has proposed dark scenarios addressing issues such as privacy, security, identity, trust, loss of control, dependency, exclusion, victimisation, surveillance, identity theft, malicious attacks, digital divide and spamming. Notably, ethical issues in AAL arise not only in the implementation phase, but also during the design, development and testing of new methods and technologies.

In addition, AAL technologies are not "static", i.e., the form and capabilities of the technologies under the umbrella of "AAL devices and services" are continually changing, both through iterations and revisions on existing devices, and through the introduction of new devices or methods. As time moves forward, the capabilities of AAL technologies continue to increase, opening up new possibilities to designers. However, as the capabilities increase, so, too, do the ethical concerns, should they not be properly considered and addressed. In order for this kind of technology to be deployed successfully and according to the fundamental rights and values of older and disabled people, an ethical assessment is required throughout the product life cycle as well as the early adoption of an ethical design approach (Bowen, 2009).

## PRIVACY AND DATA PROTECTION

While pervasive and ambient ICT may have a very important role to play in the support and protection of elderly people, particularly those who are considered to be frail and / or suffering from ill-health, it does by its nature involve ongoing collection and transmission of a constant stream of data, including medical data, about the elderly person concerned.

This raises issues about freedom, choice, consistency, consent, confinement, context, inspection, adoption, protection, transparency and so on in the context of meeting the specific needs of elderly people.

Therefore, even though monitoring is a function of the AAL and a potential benefit for assisting the elderly, the solution deployed must respect and guarantee the privacy of the end user and appropriate communication protocols must be implemented to ensure that personal data can only be accessed by those authorised to do so.

## DISTRIBUTIVE JUSTICE

If, as appears to be the case, ICT is destined to become ubiquitous and a key component of effective participation in human society, then it is essential that it be accessible by all. This is highly relevant in the case of elderly or disabled people who are being helped to live independently in their own homes for longer. The success of this objective depends on the resources needed to install, monitor and maintain the necessary ICT systems being universally available. Failure to ensure this availability to all those who need it will be a clear breach of distributive justice. Frequently it is those living in rural or remote areas who are

most likely to find access to the technology difficult, while at the same time often being those in greatest need of it.

In addition to lack of financial resources, access to ICT may be hindered by lack of education, lack of awareness and understanding or simply fear of the technology. This may well be the case for many elderly people who have little or no experience of ICT systems and may find some systems difficult to operate. According to the European Commission's 2005 Benchmarking Report, 38% of EU citizens were regular users of the Internet, but only 8% of people over 65 years of age were regular users. Hence there is a clear need to ensure an adequate and comprehensive programme of awareness-raising, practical support, familiarisation and on-going training and reassessment of an individual's capabilities, particularly where they may be deteriorating both physically and mentally.


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## ISOLATION AND EXCLUSION

Increased use of ICT as the main or only method of communicating with the outside world carries a danger of elderly people becoming increasingly isolated. Whilst some elderly people might gain from communication platforms such as Skype to keep in touch with geographically distant relatives, many, especially older, frailer and less well educated ones are unlikely to. If visits by care-givers or family members are substituted not only by cell phone calls but by remote surveillance as enabled through AAL, senior citizens can become isolated even in the most populated areas and in their own homes. Better and more effective remote observation, sensing and monitoring can also rapidly lead to less frequent visits from health and social care professionals.

These and other similar scenarios could result in increased isolation and loneliness for elderly people. Some scientists believe robots are the answer to caring for ageing societies in which the young might otherwise be overwhelmed by the surging population of senior citizens. Robots such as these are already being developed and marketed and commonly take the form of cuddly pets with a rudimentary artificial intelligence (AI) and built-in sensors enabling them to respond to both contact and a user's voice, with either motion or speech. They are also able to develop a personality based on how they are treated by their owner. At the same time, these robots can be used to monitor the safety of older people because the interaction between them and their owners can be recorded and accessed remotely.

A specific concern arises in the research phase for AAL. It has been found that elderly people, who are part of AAL research programmes, can become dependent on the application that is being tested (even though it might never be marketed) or on the attention given by the researchers. The ethics guidelines for the EU-funded Ambient Assisted Living research Joint Programme recognize this when it states:

> "When designing the involvement of primary end-users in a project, it should be taken into account that end-users may become accustomed to the special attention

> and services they receive during the project. When people become deeply involved, termination of the project may create problems. Provisions for dealing with such issues are necessary in order to avoid distress and negative reactions among end-users at the end of the project. In short, the involvement of end-users in projects requires ethical awareness and respect for their dignity and right to self-determination all through the project." (AAL Guide for Applicants, 2013)

## UNDERSTANDING OF THE SELF

By replacing human attention with machines, we may not only create situations of exclusion and isolation, but also impact on human self-understanding. Are we providing machines and virtual contacts to people who ask for warmth and human contacts? During a long life, elderly people have developed a very complex self-image. In order to maintain this, it is essential to engage in meaningful interaction with other members of society. While ICT may be able to meet many of their physical needs, to monitor them, to provide support and to keep them safe, it is unlikely to be able to provide the sense of being valued that is essential for a healthy self-image. Humans are social animals and are not meant to live in isolation; they need physical, emotional and mental interactions with other human beings. Any system which seeks to replace a physical human being with ICT solutions for monitoring and supporting the elderly in their homes must recognise this and implement strategies for ensuring that the elderly individual retains the possibility of ongoing human interaction.

## LIABILITY QUESTIONS

An additional issue that must be considered in the context of ICT is that of liability. AAL systems typically incorporate or represent adaptive and/or (semi-)autonomous systems such as service robots, which are designated to interact with lay people, e.g. in the health care assistance of elderly or disabled people. However, the nature of the direct contact of an autonomous robot with its users might pose some risk of harm to the user in cases of severe robotic failure. The complexity of adaptive robotic systems limits the control and prediction of robotic action as well as any proof of cause-impact relations from accidents. Therefore, and as long as one cannot reasonably attribute responsibility to autonomous technical systems compared to human actors, any liability problems with regard to the regulation of corresponding systems remain to be solved before service robots can enter private and nursing homes in significant numbers (Dreyer and Spieker, 2012). Although this aspect apparently belongs to legal matters, it is ultimately also an ethical issue as long as concepts for appropriate regulations are pending. Without reflecting on and addressing this problem, the end user would be left alone with unknown technical risks and without prospects for related compensations.

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